Serial No.	09/810,988
Applicant:	Gerhard Scheuch *et al.*
Filed:	March 16, 2001
Title:	DEVICE FOR THE CONTROLLED INHALATION OF THERAPEUTIC AEROSOLS
Art Unit:	3731
Examiner:	Glenn K. Dawson
Confirmation Number:	7304
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HONORABLE COMMISSIONER OF PATENTS
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132

In response to the Office Action dated February 20, 2008. I, Peter Brand, do hereby declare and say as follows:

BACKGROUND INFORMATION

1. I am a co-inventor of U.S. Patent No. 6,606,989 (hereinafter referred to as "Brand").

2. I obtained a degree in University Master Degree in Physics (Dipl. Physics.) at the Johann Wolfgang Goethe-Universität in Frankfurt, Germany in 1986 and graduated with a PhD in 1990 in Biophysics. Topic: *Development of a mobile device for the measurement of atmospheric aerosol particle size distributions.*

3. From 1987 to 1989, I was employed at the GSF – Research Centre for Environment and Health at the Insitute for Biophysical Radiation Research in Frankfurt.

4. From 1989 to 2003, I was employed at the GSF – Institute for Inhalation Biology in Munich. Germany as a senior scientist and performed clinical trials in aerosol delivery research and investigated new aerosol drug delivery technologies and influences of the breathing pattern on lung deposition.

5. From 2003 to 2007, I was employed at Inamed Research GmbH & Co. KG in Gauting, Germany as a senior scientist for managing medical writing and biometry.

6. Since 2007, I have been employed at RWTH Aachen University at the Institute for Occupational and Social Medicine in Aachen, Germany.

THE APPLICATION

7. I have read and understood the above referenced patent application, including the specification, claims and the relevant prior art.

8. The standard I used for anticipation is whether every element of a claim is disclosed in a single prior art reference.

9. The standard I used for obviousness is whether the claims would have been obvious to an ordinary person skilled in the art in light of the references cited.

10. Brand does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters.

11. Brand also does not teach or suggest adjusting flow rate or tidal volume based on inhalation parameters or controlling an air flow through an inhalation device using the inhalation device during the controlled inhalation.

12. Brand teaches "a device for deposition of a medicament in a liquid form in the lungs" (claim 1, column 4, lines 33-34). Brand uses a pre-settable volumetric flow of compressed air and flow rate that can be set "over a range from 0 to 1000 cm^3/s" (column 3, lines 39-40).

13. Brand also teaches that "setting the operating pressure of the vaporizer, for instance over a range of values from 0 to 2 bar" (column 3, lines 49-50) is possible. Timing parameters are also set. "The inhaled volume then derives from the inhalation period and the flow of inhalation" (column 4, lines 6-8). The inhalation period can be set from 0 to 20 seconds.

14. Even well trained pulmonologists are not familiar with the scientific background of aerosol particle deposition within the lungs. Offering such a broad range of inhalation parameters

that can be set by the physician and the patient prevents optimum therapy for an individual patient.

15. Even after extensive breathing training, patients typically revert to a respiratory flow rate and tidal volume that are comfortable to them. In clinical trials with conventional inhalation devices, it was shown that the incorrect breathing pattern is one of the most important errors that is made during inhalation treatment. (Giraud et al. 2002, 19:246-251, European Respiratory Journal, copy attached).

16. The Giraud reference specifically states that misuse of pressurized metered-dose inhalers is mainly due to poor coordination (see Abstract).

17. The Giraud reference also states that "there was no significant direct relationship between education and AIS, which is most likely due to the fact that education is not always successful (errors are corrected in only 50% of poor users, 50% of whom return to their 'bad habits' within a few weeks)...." (page 250). Note that AIS is an "asthma instability score" referred to in Giraud.

18. The Giraud reference also states that "[the] use of devices which alleviate coordination problems should be reinforced in pressurized metered-dose inhaler misusers." (Abstract) and "[u]se of devices that make inhalation technique easier... should be reinforced in pressurized metered-dose inhaler misusers" (page 250). The present invention makes the inhalation technique much easier, since the user no longer needs to be "coordinated" and breathe correctly.

19. Controlled aerosol delivery to the lungs can only be guaranteed when inhalation parameters are inputted into the inhalation device, as claimed in claims 25, 43 and 44.

20. Brand does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, adjusting flow rate or tidal volume based on inhalation parameters, or controlling an air flow through an inhalation device using the inhalation device during the controlled inhalation. .

CONCLUSION

Based on the above analysis, I conclude that the claims in the present patent application are not anticipated or obvious over Brand.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: August 5th 2008 By: 

Peter Brand